

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2080594	(X3) Date Survey Completed 02/10/2020
Name of Provider or Supplier Advanced Reproductive Specialists Llc	Street Address, City, State 2100 Aloma Ave Ste 100, Winter Park, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was conducted on February 10, 2020. Advanced Reproductive Specialists was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document competency assessments on 1 out of 1 testing personnel in 2018 and 2019 (A). Findings: Review of the competency records showed that there was no documentation of competencies on Testing Personnel A for 2018 and 2019. During an interview on 2 /10/20 at 2:02 PM, the Medical Technologist stated they didn't do a competency evaluation on Testing Personnel A in 2018 and 2019.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's Semen Analysis Report failed to list the location where the semen morphological evaluation was performed for 3 out of 3 (#1, 2, 3) patient reports examined. Findings: Review of the Semen Analysis Report for patients #1, #2 and #3 showed that the address of the location where the semen morphological evaluation was performed was not listed. During an interview on 2/10/20 at 2:32 PM, the Medical Technologist stated that the Semen Analysis Report did not have the address where the semen morphological evaluation was performed.